No. 98-1152

IN THE
Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, *et al.*,
Petitioners,
v.
BROWN AND WILLIAMSON TOBACCO CORP., *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

BRIEF FOR RESPONDENTS PHILIP MORRIS INCORPORATED & LORILLARD TOBACCO COMPANY

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QUESTION PRESENTED

Whether the Food and Drug Administration ("FDA") has jurisdiction to regulate tobacco products even though Congress did not intend for FDA to regulate tobacco products when it enacted the Federal Food, Drug, and Cosmetic Act, and Congress—having been repeatedly advised by FDA that it lacks jurisdiction—enacted a series of tobacco-specific statutes addressing tobacco and health, which give no role to FDA and are inconsistent with FDA's assertion of jurisdiction?

RULE 29.6 LISTING

Philip Morris Incorporated

The parent company of Philip Morris Incorporated is Philip Morris Companies, Inc. Philip Morris Incorporated has no nonwholly owned subsidiaries.

Lorillard Tobacco Company

The parent companies of Lorillard Tobacco Company are Lorillard, Inc., and Loews Corporation. Lorillard Tobacco Company has no nonwholly owned subsidiaries.

PARTIES TO THE PROCEEDINGS

The petitioners are: Food and Drug Administration, and Jane E. Henney, Commissioner of Food and Drugs.

The respondents are: Brown and Williamson Tobacco Corporation; Lorillard Tobacco Company; Philip Morris Incorporated; R.J. Reynolds Tobacco Company; Coyne Beahm, Incorporated; National Association of Convenience Stores; ACME Retail, Incorporated; United States Tobacco Company, LP; Conwood Company, LP; National Tobacco Company, LP; Pinkerton Tobacco Company, LP; Swisher International, Incorporated; Central Carolina Grocers, Incorporated; J.T. Davenport, Incorporated; North Carolina Tobacco Distributors Committee, Incorporated; The American Advertising Federation; American Association of Advertising Agencies; Association of National Advertisers, Incorporated; Magazine Publishers of America; Outdoor Advertising Association of America, Incorporated; and Point of Purchase Advertising Institute.

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OPINIONS BELOW

The opinions below are identified in the Brief for the Government ("Pet. Br."), and printed in the Appendix to the Petition for Writ of Certiorari ("Pet. App.").

JURISDICTIONAL STATEMENT

This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

This case involves the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, the Federal Cigarette Labeling and Advertising Act ("FCLAA"), 15 U.S.C. § 1331 *et seq.*, the Comprehensive Smokeless Tobacco Health Education Act

("CSTHEA"), 15 U.S.C. § 4401 *et seq.*, and the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act ("ADAMHA Amendments"), 42 U.S.C. § 300x-26. These statutes are set forth in the Appendix to Respondents' Brief in Opposition to Petition for a Writ of Certiorari ("Opp. Cert. App.").

INTRODUCTION

In 1996, FDA declared that it has jurisdiction to regulate tobacco products under the FDCA, and issued regulations governing their labeling, advertising, and retail sale. Respondents challenged FDA's assertion of jurisdiction and its regulations. The district court held that the FDCA authorizes FDA to assert jurisdiction but invalidated FDA's advertising regulations. *See Coyne Beahm, Inc. v. FDA*, 966 F. Supp. 1374, 1397-1400 (M.D.N.C. 1997) (Pet. App. 76a). The United States Court of Appeals for the Fourth Circuit reversed on the threshold jurisdictional issue. It held that Congress never intended the FDCA to grant FDA jurisdiction over tobacco products as customarily marketed. *See Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155 (4th Cir. 1998) (Pet. App. 1a).

The question at issue is whether Congress granted FDA the authority to regulate tobacco products as customarily marketed.[1] The Government argues that this question is answered exclusively by the definition section of the FDCA. The court of appeals expressly disagreed, correctly concluding that this case can be decided only by looking at the statute as a whole and at Congress' historical treatment of tobacco and health. *Brown & Williamson*, Pet. App. at 14a. The Government ignores or trivializes that history. However, that "historical background . . . is essential to a proper interpretation of the Act's present text." *Department of Commerce v. United States House of Representatives*, 119 S. Ct. 765, 775 (1999). It shows unequivocally that Congress never intended to delegate to FDA the authority to regulate tobacco products, but chose instead to regulate those products itself through a series of tobacco-specific statutes.

[1] The phrase "as customarily marketed" refers to tobacco products with claims of "smoking pleasure" and similar claims, as opposed to health-benefit claims. *See e.g.* Letter from Acting FDA Comm'r Novitch for FDA Comm'r Goyan to Banzhaf, Jt. App. at 54. ("Novitch Letter") (Nov. 25, 1980). All references herein to "tobacco products" are to such products as customarily marketed.

SUMMARY OF ARGUMENT

Not satisfied with Congress' regulation of tobacco products, FDA set out in 1996 to create a new national tobacco policy. It announced that tobacco products fall within the FDCA's definitions of "drug" and "device" based on its finding that such products are "intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(C) and (h)(3).[2] FDA took this action even though:

(1) When Congress enacted the FDCA in 1938, it did not intend for FDA to regulate tobacco products—such products are not among the several product categories to which the FDCA expressly applies, and Congress did not discuss or debate applying the FDCA to tobacco products;

(2) FDA's contemporaneous construction of the FDCA was that it lacked authority over tobacco products;

(3) Immediately after the 1964 Surgeon General's Report on smoking, FDA once again told Congress that it lacked authority over tobacco products, and advised Con-

[2] The brief filed by R.J. Reynolds Tobacco Company shows that the FDCA as a whole cannot be read to apply to tobacco products. The briefs filed by Brown and Williamson Tobacco Corporation and United States Tobacco Company, *et al.*, demonstrate why tobacco products do not meet these definitions.

gress that granting FDA such authority would likely result in a ban;

(4) Given this understanding, Congress *rejected* proposals to give FDA such authority and instead enacted the Federal Cigarette Labeling and Advertising Act ("FCLAA"), which requires congressionally-authored warnings on cigarette packages and reserves to Congress authority to address smoking and health;

(5) After enactment of the FCLAA, FDA expressed its understanding that Congress had reserved to itself the authority to regulate health issues regarding tobacco products, an understanding that Congress itself confirmed by exempting such products from the authority of other federal health agencies that had not, as had FDA, already disavowed jurisdiction over those products;

(6) As new information respecting tobacco and health was presented to Congress, it adopted additional legislation specifically regulating the labeling and advertising of tobacco products, and creating incentives for the States to control their retail sale—without providing any role for FDA;

(7) While acting upon tobacco-specific legislation and at other times, Congress considered, but never enacted, legislation to grant FDA authority over tobacco products.

In the face of this history, FDA nonetheless asks this Court to hold that, in 1938, Congress silently—indeed, unwittingly—authorized FDA to regulate and ban tobacco products. This position is contrary to FDA's disavowals of any authority over tobacco products, which it repeatedly communicated to Congress and which were a predicate for Congress' enactment of tobacco-specific statutes.

In these enactments, Congress expressly *reserved to itself* the power to regulate health issues regarding tobacco

products—either directly or by carefully delineating limited, non-policymaking roles for certain federal agencies—but provided no role for FDA. In legislating national tobacco policy, Congress has addressed the same aspects of tobacco-product labeling, advertising and sale that FDA now seeks to regulate by administrative fiat. FDA's assertion of jurisdiction neither fills a gap in the FDCA nor comports with the purpose or operative provisions of that Act. Rather, "[i]t is effectively the introduction of a whole new regime of regulation . . . which . . . is not the one that Congress established." *MCI v. AT&T*, 512 U.S. 218, 234 (1994).

Simply put, FDA's assertion of jurisdiction cannot be reconciled with Congress' policy as embodied in its tobacco-specific legislation. Congress and FDA itself repeatedly have recognized that a principled application of the "drug" or "device" provisions of the FDCA to tobacco products would result in their prohibition because tobacco products could not meet the Act's safety requirement. But a national ban on tobacco products—like many other aspects of FDA's assertion of jurisdiction—would directly and unavoidably conflict with the tobacco-specific legislation enacted by Congress.

The relevant history and these irreconcilable conflicts establish that Congress never intended that tobacco products be subject to the FDCA. In disregarding that intent, FDA has usurped Congress' legislative powers.

ARGUMENT

I. CONGRESS HAS NEVER GIVEN FDA AUTHORITY OVER TOBACCO PRODUCTS, BUT INSTEAD HAS CHOSEN TO REGULATE TOBACCO PRODUCTS IN WAYS THAT ARE FUNDAMENTALLY INCOMPATIBLE WITH FDA JURISDICTION.

FDA defends its assertion of jurisdiction with the remarkable claim that Congress always intended that FDA

could regulate tobacco products under the FDCA. *See* 61 Fed. Reg. 44,396, 45,253 (1996). Yet this claim makes pointless Congress' consideration for many years of who should regulate tobacco products and how. In fact, FDA repeatedly told Congress that the FDCA does not extend to tobacco products. Given this understanding, no fewer than thirty-six bills have been introduced in Congress to grant FDA jurisdiction over tobacco products, reflecting congressional understanding that new legislation would be necessary to confer such jurisdiction. But Congress never enacted such legislation.

Rather, after much discussion, Congress created its *own* legislative program specifically addressing the issue of tobacco and health. This legislation responds to the very concerns FDA relies on to justify its assertion of jurisdiction—youth access, the influence of tobacco advertising, and the pharmacological effects of tobacco products on the body, including nicotine "addiction."

As FDA and the Justice Department acknowledged, "[t]he participants in these [congressional] discussions [on tobacco] . . . would be shocked to learn that during all this time FDA has had jurisdiction to regulate cigarettes as drugs, and presumably to ban them." Brief for Gov't Appellee (FDA) (*"FDA/DOJ Brief"*)[3] at 40, *ASH v. Harris*, 655 F.2d 236 (D.C. Cir. 1980).

A. Federal Food and Drug Laws Were Never Intended to Cover Tobacco Products as Customarily Marketed.

The federal food and drug laws—and the view that they do *not* apply to tobacco products—go back nearly 90 years. In 1906, Congress passed the Pure Food and

[3] Respondents have lodged with the Court a compilation of materials referenced herein, excluding judicial decisions, statutes, and regulations.

Drug Act, Pub. L. No. 59-384, 34 Stat. 768 (1906). Nothing in the language or legislative history of that early legislation indicates that Congress intended it to govern tobacco products. Indeed, FDA's predecessor, the Bureau of Chemistry in the Department of Agriculture, announced that it could *not* regulate tobacco products unless they were marketed with medical claims. Bureau of Chemistry, U.S. Dep't of Agriculture, *Service & Regulatory Announcements, No. 13* (Apr. 2, 1914).

When this announcement was made, concerns about the health effects of tobacco were widespread, and scientific reports already had identified the pharmacological effects of nicotine.[4] Between 1895 and 1921, fourteen states banned cigarettes entirely; and all the others prohibited their sale to minors.[5] This Court upheld such a cigarette ban in *Austin v. Tennessee*, 179 U.S. 343, 348 (1900), observing that the "belief in [the] deleterious effects [of 'cigarettes'] . . . has become very general." *See also Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 513 (1992) (noting that "physicians had suspected a link between smoking and illness for centuries"). A few years later, some members of Congress proposed to amend the 1906 Act to cover tobacco products. *See* S. 1468, 71st Cong. (1929); 71 Cong. Rec. 2589 (1929). But that proposal—like every similar proposal since—was not enacted.

[4] *See, e.g.*, Henningfield & Jasinski, *Pharmacologic Basis for Nicotine Replacement, in* Nicotine Replacement: A Critical Evaluation 35-36 (Pomerleau, *et al.* eds., 1988) ("[P]harmacologic studies of the psysiologic actions of nicotine were well underway by the 19th century. By the beginning of the 20th century, there was little scientific question that nicotine was the pharmacologic mediator of many effects of tobacco sought by its users.").

[5] *See* Nuehring & Markle, *Nicotine and Norms: The Re-Emergence of a Deviant Behavior, in* 21 Social Problems 513, 515 (1974); 1899 Tex. Gen. Laws Ch. 139 § 1 (*codified at* Tex. Penal Code art. 1049 (1911)).

Nor did Congress intend to authorize FDA to regulate tobacco products when it enacted the FDCA in 1938. The FDCA identifies the four categories of products to which it applies: foods, drugs, devices, and cosmetics. Tobacco products are not among them, even though at the time of its enactment tobacco products outsold pharmaceuticals three-to-one, 37% of American adults smoked cigarettes, and tobacco excise taxes accounted for ten percent or more of federal tax revenues.[6] Moreover, the federal government recognized tobacco as a separate sector of the economy. *See, e.g.*, U.S. Dept. of Commerce, *Statistical Abstract of the United States*, 178-9 (1939). If Congress had intended the FDCA's "drug" and "device" provisions to encompass so significant a category as tobacco products, the legislative history surely would reflect it.

But there is *nothing* in the language or legislative history of the Act suggesting this intent. "If Congress intended such a result, its failure even to hint at it is spectacularly odd." *Medtronic v. Lohr*, 518 U.S. 470, 491 (1996). It is "not plausible to interpret the statutory silence as tantamount to an implicit congressional intent" that FDA regulate tobacco products. *Central Bank of Denver v. First Interstate Bank of Denver*, 511 U.S. 164, 185 (1994). Even the Government does not argue that Congress in 1938 envisioned that tobacco products were within the scope of the FDCA, and it concedes that there was "no discussion in the legislative history of the 1938 Act" respecting its potential application to tobacco products. Pet. Br.

[6] U.S. Dep't of Commerce, Bureau of the Census, *Historical Statistics of the United States: Colonial Times to 1970*, 319 (H.R. Doc. No. 93-78, 1973); U.S. Dep't of Health and Human Services, Public Health Service, *The Health Consequences of Smoking to Women, A Report of the Surgeon General* 23 (1980); U.S. Dep't of Commerce, Bureau of the Census, *Statistical Abstract of the United States 1938*, at 179 (Table 181) (1939).

at 22, n.4.[7] *Cf, Amoco Prod. Co. v. Southern Ute Indian Tribe*, 119 S. Ct. 1719, 1724-27 (1999) (examining the historical context of the relevant statute).

Had there been any suggestion in 1938 that the FDCA might apply to tobacco products:

> Congress would have made it explicit in the statute, or at least some of the Members would have identified or mentioned it at some point in the unusually extensive legislative history . . . . "In a case where the construction of legislative language such as this makes so sweeping and so relatively unorthodox a change, . . . judges as well as detectives may take into consideration the fact that a watchdog did not bark in the night."

Chisom v. Roemer, 501 U.S. 380, 396, n.23 (1991). Indeed, the Senate and House Conference Committee managers *supporting* passage of the FDCA included Members from the two leading tobacco States—North Carolina and Kentucky. *See* 83 Cong. Rec. 9094 (1938).

Congress' silence cannot be attributed to a lack of legislative interest in tobacco. Since at least the turn of the century, Congress has regulated tobacco products separately from foods, drugs, devices, and cosmetics. *See, e.g.*, Pub. L. No. 57-237, §§ 1-2, 32 Stat. 714 (1902)

[7] Far from creating an "overwhelming implication" that the FDCA covers tobacco products, Pet. Br. at 19, this congressional silence at most reflects Congress' understanding that tobacco products, like other non-medical products, are subject to the FDCA only if manufacturers or vendors make therapeutic claims. *See United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 848-49 (D.N.J. 1959); *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336, 337 (D.N.J. 1953). In the present case, FDA asserted jurisdiction "regardless of whether manufacturers make express claims of therapeutic value," Pet. Br. at 15, and FDA has not alleged that any of the respondents make such claims. 61 Fed. Reg. 44,396, 45,194 (1996).

(cigarette packaging); Pub. L. No. 61-5, §§ 30-35, 36 Stat. 108-11 (1909) (cigarette packaging, marketing, and sale); Pub. L. No. 73-483, §§ 1-13, 48 Stat. 1275 (1934) (cigarette production, marketing, and consumption); Pub. L. No. 74-314, §§ 2-3, 49 Stat. 731 (1935) (cigarette marketing). Congress even passed *separate* tobacco legislation in the same year it passed the FDCA. *See* Pub. L. No. 75-430, 52 Stat. 31 (1938). Thus, it is no surprise that the 1938 Congress "did not endeavor to break away from the traditional understanding," *Murphy Bros., Inc. v. Michetti Pipe Stringing, Inc.*, 119 S. Ct. 1324, 1327 (1999), that tobacco products are separate from foods, drugs, devices, and cosmetics.

FDA's original understanding that the FDCA does not cover tobacco products reflected its own extensive involvement in drafting the FDCA—preparing the initial bill, testifying on it and successor bills, and explaining to Congress how the "drug" and "device" definitions of the Act would operate.[8] In light of that involvement, in the two decades following enactment of the FDCA, FDA consistently reiterated its understanding and "repeatedly informed Congress that cigarettes were not comprehended by the statutory definition of the term 'drug' absent

[8] The "original bill leading to the enactment of the [FDCA] . . . was prepared in the U.S. Dept. of Agriculture," which was the parent department of FDA (and FDA's predecessor, the Bureau of Chemistry). Dunn, *Federal Food, Drug, and Cosmetic Act*, 24 (1938). *See e.g., Food, Drugs and Cosmetics: Hearing on S. 1944 Before a Subcomm. of the Senate Comm. on Commerce*, 73d Cong. 15-16 (1934) (remarks of FDA Chief Campbell regarding meaning of definitions); *Food, Drugs, and Cosmetics, 1934: Hearings on S. 2800 Before the Senate Comm. on Commerce*, 73d Cong. 516-518 (1934) (same); *Food, Drugs, and Cosmetics, 1935: Hearing on H.R. 6906, H.R. 8805, H.R. 8941 and S. 5 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 74th Cong. 55-56 (1935) (same).

health claims on behalf of the manufacturer or vendor." *FDA/DOJ* Brief at 16, 22 n.19. This history demonstrates that FDA's prior position "that cigarettes are beyond the scope of the [FDCA] absent health claims" "accords with congressional intent in drafting the statute." *Id.* at 14-15.

As the Justice Department explained:

> [C]orrespondence dating from at least as early as 1940, show that [FDA's] interpretation was in accordance with the *contemporaneous construction* of the 1938 Act by the persons charged with its administration.

Id. at 22, n.19 (emphasis added). "This contemporaneous administrative construction of the act is persuasive of the original" congressional "understanding, especially in light of the extensive role the [agency] played in drafting the statute and explaining its operation to Congress." *Howe v. Smith*, 435 U.S. 110, 131 (1981); *see also United States v. American Trucking Ass'ns*, 310 U.S. 534, 549 (1940).

B. In the 1960s, Congress Rejected the Option of Granting FDA Authority to Regulate Tobacco Products, and Instead Enacted Its Own Regulatory Program that Provided No Role for FDA.

Congress addressed the possible health implications of tobacco products in the 1960s. Indeed, Congress was aware of the same concerns now raised by FDA to justify its assertion of jurisdiction: youth access, tobacco advertising, and the pharmacological effects of nicotine, *e.g.*, "addiction."[9] In response to such concerns, Mem-

[9] *See, e.g.*, 109 Cong. Rec. 7,455 (1963) (Rep. Udall expressing concern over reports by "leading medical authorities" of the "harmful, and in fact deadly, effects of cigarette smoking" and "the increasing tempo of advertising in all media designed to lure young people into the use of cigarettes"); 108 Cong. Rec. 10,053 (1962)

bers of Congress again expressed interest in federal regulation of tobacco products, and introduced bills to amend the FDCA to grant FDA jurisdiction over cigarettes.[10] These bills were introduced precisely because it was clear that "smoking products do not come under the protection of the FDA." 109 Cong. Rec. 10,318 (1963) (Sen. Moss). Again, however, Congress did not give FDA jurisdiction over tobacco products.

At the same time, FDA repeated its position that it could not regulate tobacco products unless they were sold with therapeutic claims. In 1963, FDA referred to "the exclusion of tobacco products from FDA's jurisdiction," and stated that: "tobacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions in the [FDCA] for food, drug, device or cosmetic." Letter from FDA Bureau of Enforcement to Directors of Bureaus, Divisions and Directors of Districts (May 24, 1963) *in Public Health Cigarette Amendments of 1971: Hearings on S. 1454 Before the Consumer Subcomm. of the Senate Comm. on Commerce*, 92nd Cong. 240 (1972).

In 1964, the Advisory Committee to the Surgeon General on Smoking and Health issued its landmark "Report on Smoking and Health." U.S. Dep't of Health, Education and Welfare, Public Health Service, *Smoking and Health, Report of the Advisory Committee to the Surgeon General of the Public Health Service* (1964) ("1964

(Senator Neuberger noting statement of American Cancer Society official that "smoking is 'truly and in all respects an addiction,'" and that "help is needed to 'prevent new recruitment to smoking among the young'").

[10] S. 1682, 88th Cong. (1963); H.R. 5973, 88th Cong. (1963); H.R. 9512, 88th Cong. (1963). Even prior to the 1960s, bills had been introduced to amend the FDCA to grant FDA authority over cigarettes. H.R. 11280, 84th Cong. (1956); S. 2554, 85th Cong. (1957); H.R. 592, 85th Cong. (1957). None of these bills were enacted.

Surgeon General Report"). The publicity was enormous, and Congress' response was swift. Legislation to permit FDA to regulate tobacco products was proposed, but Congress instead chose an entirely different course—it enacted the Federal Cigarette Labeling and Advertising Act ("FCLAA").

Hearings on the FCLAA commenced in 1964, shortly after the release of the Surgeon General's Report. Chairman Harris of the House Committee on Interstate and Foreign Commerce announced:

> The purpose of these hearings will be . . . to determine the extent of authority under existing law to deal with [the issue of tobacco and health,] and to determine whether any action of the Congress is warranted in the interest of public health.

Cigarette Labeling and Advertising: Hearings Before the House Comm. on Interstate and Foreign Commerce, 88th Cong. 23 (1964) ("*1964 Hearings*").[11] When asked whether the Department of Health, Education and Welfare ("HEW") (FDA's parent) "presently has authority to brand or label the packages of cigarettes or to control the advertising," Surgeon General Terry responded without qualification: "we do not have such authority in existing laws governing the Public Health Service and Food and Drug Administration." *Id.* at 56.

[11] There "was no question at the time of the 1964 [Surgeon General's] Report that nicotine was the critical pharmacologic agent for tobacco." U.S. Dep't of Health and Human Services, Public Health Service, *The Health Consequences of Smoking: Nicotine Addiction, A Report of the Surgeon General*, 10 (1988); *1964 Surgeon General Report*, at 69-75 (discussing scientific research regarding pharmacological effects of nicotine, including "stimulation," "tranquilization" and "suppression of appetite").

Congress specifically considered youth smoking and advertising: "[S]ome 4,500 boys and girls between the ages of 12 and 17 take up the habit each day of the year." *1964 Hearings* at 34; *see also id.* at 16-17, 25-26, 31, 293-94.

Even those Members who believed that FDA should address smoking and health understood that the existing FDCA did not give FDA such authority. Instead, they introduced legislation to *grant* it such authority. *See id.* at 4-7.

However, HEW Secretary Celebrezze opposed those bills on the ground that FDA jurisdiction over cigarettes would likely result in their ban:

> In light of the Advisory Committee's report on smoking and health, this provision might well completely outlaw at least cigarettes. This would be contrary to what, we understand, is intended or what, in the light of our experience with the 18th Amendment, would be acceptable to the American people.

Id. at 18. When Chairman Harris later observed that the one remaining bill to give FDA jurisdiction would lead to a tobacco ban, Rep. Udall, its sponsor, said he did not intend that result, and abandoned his bill. *Cigarette Labeling and Advertising—1965: Hearing on H.R. 2248 Before the House Comm. on Interstate and Foreign Commerce*, 89th Cong. 29 (1965) ("*1965 Hearings*").

Shortly thereafter, FDA again testified that it "has no jurisdiction under the [FDCA] over tobacco, unless it bears drug claims." *Id.* at 193 (statement of FDA Deputy Comm'r Rankin). Although another bill was introduced to give FDA jurisdiction over cigarettes, H.R. 2248, 89th Cong. (1965), it did not pass. Thus, as it debated how best to respond to the Surgeon General's Report, Congress actively considered—then squarely rejected—any FDA involvement.

Instead, Congress enacted the FCLAA and made clear that it was retaining for itself sole authority to balance the important competing societal interests and to determine the appropriate federal regulation of cigarettes:

> *The determination of appropriate remedial action in this area . . . is a responsibility which should be exercised by the Congress* after considering all facets of the problem. The problem has broad implications in the field of public health and health research, and involves potentially far-reaching consequences for a number of sectors of our economy.

H.R. Rep. No. 89-449, 3 (1965) (emphasis added). Indeed, Congress took the step of announcing *in the statutory text* its overriding policy and purpose

> *to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health,* whereby . . . the public may be adequately informed that cigarette smoking may be hazardous to health by inclusion of a warning to that effect . . . and . . . commerce and the national economy may be . . . protected to the maximum extent consistent with this declared policy . . . .

Pub. L. No. 88-92, § 2, 79 Stat. 282 (1965), *codified at* 15 U.S.C. § 1331 (emphasis added).

Congress' intent to withhold jurisdiction from FDA is further confirmed by the outcome of a broader debate over whether *any* administrative agency should be given any policymaking authority over smoking and health. Arguing for administrative flexibility, the FTC Chairman, the HEW Secretary, and the Surgeon General presented options for delegating new regulatory authority over tobacco to federal agencies. *1965 Hearings* at 38, 78-79. Several Members and witnesses expressed support for that view; others were opposed. *See e.g., id.* at 168-70, 240, 445-46; *Cigarette Labeling and Advertising: Hearings Before the Senate Commerce Comm. on S. 559 and S. 547*, 89th Cong. at 405, 636, 692 (1965); 110 Cong. Rec. 15000-01 (1964).

As Rep. Rogers of Texas, author of the bill that passed the House, 111 Cong. Rec. 13900 (1965), and a Conference Committee member, *id.* at 13913, put the issue:

> [T]he main issue here is who is going to put the reins on the situation involving an industry that is very important in this country at the present time from an economic standpoint, if reins are needed.
>
> * * * *
>
> [M]y bill was introduced for the purpose of laying down a situation that the Congress of this country, made up of the duly elected representatives under the Constitution, are still the ones who are supposed to set policy in this field.

1965 Hearings at 218.

Chairman Harris, manager of the FCLAA in the House, also addressed the "who" question: "I think it is a job for the Congress to do and not an executive agency or a regulatory agency through its own action. . . ." 111 Cong. Rec. 13900 (1965).

Sen. Hartke observed that "much of the time during the hearings" was devoted to considering whether the FTC

> *or any other federal administrative agency* created by Congress should be permitted, [by] expanding authority delegated to it by Congress . . . to *usurp the authority of the Congress* in an area of national importance.

111 Cong. Rec. 13431 (1965) (emphasis added).

The FCLAA thus reflects Congress' decision to reserve to itself the decision-making responsibility for setting national policy respecting tobacco and health. Exclusion of FDA from regulation of cigarettes was indispensable to Congress' program because, as HEW Secretary Celebrezze had told Congress in 1964, FDA jurisdiction probably would lead to a ban. Given that understanding, the FCLAA "clearly bar[s] any expansion," *Northwest Bank Worthington v. Ahlers*, 485 U.S. 197, 206 (1988), of the FDCA to encompass tobacco products.

The policy established in the FCLAA—that cigarettes may be advertised and sold to adults but that smokers

must be informed of possible health hazards through warnings drafted by Congress—reflects Congress' balancing of health, consumer liberty, and "commerce and the national economy." FDA's assertion of jurisdiction—which under the FDCA would lead to a ban—would nullify that statutory scheme. Apart from a ban, FDA's authority over product labeling under the FDCA is inconsistent with the FCLAA labeling provisions. *Cf. Int'l Bhd. of Teamsters v. Daniel*, 439 U.S. 551, 567-70 (1979) (enactment of ERISA confirms SEC's lack of authority to reverse its prior understanding and expand its jurisdiction).

C. During the 1970s, FDA Reaffirmed that It Lacked Authority to Regulate Tobacco Products, and Congress Continued to Develop Its Own Regulatory Program, and to Exclude Agency Policymaking, on Tobacco and Health.

In 1969, Congress revisited the FCLAA and again focused on the issues of youth access, tobacco advertising, and "addiction." For example, one Member advised his colleagues, "The statistics indicate that 4,000 children every day are newly hooked on smoking." *Cigarette Labeling and Advertising—1969 (Part 1): Hearings on H.R. 643, H.R. 1237, H.R. 3055, H.R. 6543 Before the House Comm. on Interstate and Foreign Comerce*, 91st Cong. 47 (1969) ("*1969 Hearings*"). John Banzhaf, a founder of Action on Smoking and Health ("ASH"), testified that there was "substantial medical evidence" that "smoking to many people can be as addicting in the physical and medical sense as heroin . . . ." *Id.* at 288.

Congress responded by amending the FCLAA to prohibit broadcast advertisements for tobacco products and by strengthening the warning on cigarette packs. Pub. L. No. 91-222, § 6, 84 Stat. 87, 89 (1970).[12] Congress also

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[12] The legislative history of the 1970 Amendments contains numerous comments on the need to discourage underage smoking and

reaffirmed that federal tobacco policy was a matter for Congress—not administrative agencies. The House Report states:

> The regulations [proposed by the FTC and FCC would] . . . cut across the whole spectrum of commercial and social life in the United States. It is therefore an area where the Congress, if anyone, must make policy.
>
> * * * *
>
> Therefore, the committee feels that it is incumbent on the Congress to act on the reported legislation in order to prevent [administrative] intrusion . . . into basic areas of policymaking *which it has reserved to itself.*"

H.R. Rep. No. 91-289, 5 (1969) (emphasis added). Thus, Congress disparaged the "assumption by these agencies of policymaking with respect to a subject matter on which Congress has made policy [and] has stated its intention to be the exclusive policymaker." *Id.*

Two years later, FDA again advised Congress that it had no jurisdiction over tobacco products under the FDCA and that such jurisdiction would necessitate a ban:

> [C]*igarettes recommended for smoking pleasure are beyond the* [FDCA]. . . . Indeed, if cigarettes were to be classified as drugs, they would have to be removed from the market because it would be impossible to prove they were safe for their intended use. . . .

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cigarette advertising that appealed to youth. *See 1969 Hearings* 91st Cong. at 44-47, 54, 57, 69, 72-88, 169-70, 193, 224, 229, 263-64, 279, 286-89, 298-302, 314, 356, 273, 381, 430, 447, 451, 467, 471, 476, 484-90, 494, 497, 501-02, 601, 615-18, 625-35, 644-45, 679, 728-29, 737-38, 1201, 1287-88, 1291, 1303-07, 1340-41, 1350, 1371-72, 1376 (1969); *Cigarette Advertising and Labeling: Hearings on H.R. 6543 Before the Consumer Subcomm. of the Senate Comm. on Commerce*, 91st Cong., 33, 47-48, 76-79, 84-87, 98-99, 117, 121-22, 135, 156, 181 (1969).

> [W]e believe [the FCLAA] demonstrates that *the regulation of cigarettes is to be the domain of Congress.* . . . In sum, labeling or banning cigarettes is a step that can be take[n] only by the Congress. Any such move by FDA would be inconsistent with the clear congressional intent.

Public Health Cigarette Amendments of 1971: Hearings on S. 1454 Before Consumer Subcomm. of the Senate Comm. on Commerce, 92nd Cong. 246 (1972) (emphasis added) (Statement of FDA Comm'r Edwards). FDA further acknowledged that Congress decided in the FCLAA

> that cigarettes should not be banned, that they should be allowed to remain in commerce with the warnings decided on by Congress [and] we have no basis for making any kind of determination *literally contrary to the congressional determination.*

Id. at 245 (Statement of FDA Chief Counsel Hutt). Shortly thereafter, the FDA Chief Counsel, after consultation with the General Counsel of HEW, stated that "a test case [asserting FDA jurisdiction over cigarettes] would be without sound legal basis, and thus should not be instituted." *Id.* at 242 (letter from Chief Counsel Hutt to Sen. Moss).

By the early 1970s, Congress had established, and FDA had acknowledged, two fundamental propositions: First, Congress itself would regulate the health aspects of tobacco products through specific legislation that balanced health concerns with other factors, including the freedom of adults to smoke and the importance of tobacco to the national economy. Second, FDA would have no role in regulating tobacco products. Indeed, FDA's testimony reflects its understanding that, through the FCLAA, Congress had reserved such authority to itself. Thus, FDA's current assertion of jurisdiction over tobacco products

defies Congress' intent that no federal agency shall have authority to fashion federal tobacco and health policy.

Congress' intent to exclude administrative competition in the development of federal tobacco and health policy is expressed not only in the FCLAA; it is also manifest in post-FCLAA product safety statutes that expressly exclude tobacco products.[13] FDA, of course, had made it clear that it could not regulate tobacco products. However, the same assurance could not be provided for a new agency, the Consumer Product Safety Commission ("CPSC"), which Congress created in 1972, pursuant to the Consumer Product Safety Act ("CPSA"), Pub. L. No. 92-573, 86 Stat. 1207 (1972) *codified at* 15 U.S.C. § 2051 *et seq.* So, Congress expressly excluded "tobacco products" from the CPSC's jurisdiction. *Id.* at § 2052(a)(1)(B).[14]

In 1976, Congress twice again precluded the possibility of agency interference with Congress' regulation of tobacco products. The CPSC had been ordered by a U.S.

[13] The Government asserts that the FDCA's failure to expressly exclude tobacco products indicates that Congress never intended to bar FDA from regulating them. Pet. Br. at 19. To the contrary, FDA's repeated testimony to Congress that it lacked authority over tobacco products fully explains why, during this period, Congress did not have to consider amending the FDCA to explicitly exempt tobacco products. The Government's attempt to make affirmative use of the statutes that preclude administrative regulation of tobacco products ignores the unmistakable congressional policy which they embody—that no federal agency may regulate tobacco product health and safety absent specific congressional direction.

[14] The CPSA was the product of competing bills. The House version that prevailed transferred from FDA to the CPSC responsibility over the Federal Hazardous Substances Act, *codified at* 15 U.S.C. § 1261 *et seq.*—which, among other things, provides that a hazardous substance may be banned. 15 U.S.C. § 2052(a)(1)(B). The Senate bill would have created a super product-safety agency built around FDA and the statutes for which it was then responsible—the FDCA and the FHSA. *See* S. Rep. 92-749, 12 (1972).

district court to consider the merits of a petition to ban high-tar cigarettes pursuant to the Federal Hazardous Substances Act ("FHSA"). Before the CPSC acted, Congress amended the FHSA to add an exclusion for tobacco products similar to the one it had adopted in the CPSA four years earlier. FDA understood the message that Congress intended to send, for it later interpreted the exclusion of tobacco products from FHSA as "indicative of the policy of Congress to limit regulatory authority over cigarettes by Federal Agencies." Novitch Letter, Jt. App. at 59.

A few months later, agency jurisdiction over tobacco arose again during Congress' consideration of the Toxic Substances Control Act ("TSCA"), Pub. L. No. 94-469, Title I, § 2, 90 Stat. 2003 (1976), *codified at* 15 U.S.C. § 2601 *et seq.*, which empowers the EPA to regulate and, if appropriate, to ban toxic chemical substances. Uncertain about how the EPA might apply this new authority, Congress excluded "tobacco or any tobacco product" from the TSCA. 15 U.S.C. § 2602(2)(B)(iii).

The import of these actions by Congress is unmistakable: After making FDA's confirmation that the FDCA could not apply to tobacco products a predicate of its own program in the FCLAA, Congress took the additional steps necessary to assure that no other federal agency could usurp Congress' control of federal tobacco and health policy.[15]

The statutory landscape was thus settled by 1976 when Congress passed the Medical Device Amendments to the

[15] The public health acts passed by Congress in the 1970s also demonstrate Congress' continued understanding that tobacco products are separate from those products regulated under the FDCA. *See* 15 U.S.C. § 1261 (separately excluding "tobacco and tobacco products" and food, drugs, devices, and cosmetics from the FHSA); *id.* at § 2052 (separately excluding same product categories from the CPSA); *id.* at § 2602(2)(B) (separately excluding same product categories from the TSCA).

FDCA, Pub. L. No. 94-295, 90 Stat. 539 (1976). Nothing in the text, structure, or history of these amendments even hints that the same Congress that had precluded EPA and the CPSC from regulating tobacco products intended to give FDA the tools to do so. FDA itself stated:

> [*T*]*here is no evidence in the legislative history . . . that Congress intended to include cigarettes within the definition of "device"* nor does the legislative history contain any discussion of a possibility that cigarettes were "devices" within the prior definition.
>
> The amendments were thoroughly considered, and the legislative history discusses the types of products intended to be regulated and the types of health hazards with respect to which the amendments were intended to provide authority. Cigarettes are not mentioned even though Congress was aware of the considerable public discussion of the health hazards of cigarette smoking.

Novitch Letter, Jt. App. at 54 (emphasis added). Only a year later, FDA again declared that it had "*no authority to regulate*" cigarettes. 42 Fed. Reg. 19,996, 20,001 (1977) (emphasis added).

In May 1977, ASH petitioned FDA to regulate cigarettes as "drugs" on the ground that they contain nicotine, which ASH contended produces a "physical addiction" in many smokers, including young smokers. *Citizen Petition*, FDA Dkt. No. 77P-0185 at 4-11 (May 26, 1977). This was the same argument ASH had presented to Congress in 1969 prior to its amending the FCLAA—and that FDA now invokes to justify its assertion of jurisdiction.

In fact, most of the arguments FDA now advances as "new" grounds for asserting jurisdiction over cigarettes, *see* 61 Fed. Reg. 44,396, 45,226 (1996), were presented to FDA in ASH's 1977 petition, just as they had been presented to Congress in the 1960s:

- the nicotine in cigarettes is a drug (p. 2);
- "studies have demonstrated that many smokers smoke largely for the physiological effects the drug causes on their body" (p. 2);
- "[n]umerous medical and other studies treat nicotine as a drug no different in many of its effects than heroin and other addictive substances" (p. 2);
- "overwhelming persuasive evidence" shows that "cigarettes are 'intended to affect the functions of the body' by many users as well as by the manufacturers" (p. 2);
- "[n]icotine is an extremely powerful substance exerting powerful effects . . . on the brain, spinal cord, peripheral nervous system, the heart, lungs and various other bodily structures" (p. 6);
- "[s]tudies going back at least to 1940 . . . indicate that for many smokers the act of smoking is merely a convenient and socially accepted manner of administering a carefully-controlled dose of nicotine to the body" (pp. 7-8);
- a "cigarette, is after all, an instrument, apparatus, or contrivance *designed* to administer controlled amounts of nicotine and other substances to the smoker upon demand" (p. 31) (emphasis added); and
- "most children have no trouble acquiring the product" (p. 36).

In rejecting the ASH petition, FDA did not dispute *any* of ASH's factual assertions. Instead, it rejected the petition *as a matter of law* on the ground that such allegations, *even if true*, could not authorize FDA to regulate cigarettes. FDA confirmed that its "interpretation of the [FDCA] . . . *consistently has been that cigarettes are not a drug unless health claims are made by the vendors.*" Letter from FDA Comm'r Kennedy to Banzhaf, Jt. App. at 47 (Dec. 5, 1977) (emphasis added). Accord-

ing to FDA, "citations in the petition that cigarettes are used by smokers to affect the structure or any functions of their bodies *are not evidence* of such intent by the manufacturers or vendors of cigarettes . . ." *Id.*, Jt. App. at 48-49 (citation omitted) (emphasis added).

When ASH challenged in court FDA's rejection of its petition that FDA regulate cigarettes as "contrivance[s] designed to administer controlled amounts of nicotine," *Citizen Petition* at 31, FDA and the Justice Department defended the Agency's determination that it lacked jurisdiction over cigarettes:

> In the 73 years since the enactment of the original Food and Drug Act, and in the 41 years since the promulgation of the modern Food, Drug, and Cosmetic Act, the FDA has repeatedly informed Congress that cigarettes are beyond the scope of the statute absent health claims establishing a therapeutic intent on behalf of the manufacturer or vendor.

FDA/DOJ Brief at 14-15. Although "the hazards of smoking, including its addictive effects, were known in 1952," *id.* at 29, n.24, FDA and the Justice Department stated:

> Since at least the issuance of the Surgeon General's Report on smoking in 1964, cigarettes have been at the forefront of discussions of the public health—in Congress, in the Executive Branch, in the news media, and among the public generally. *The participants in these discussions over the past 15 [now 35] years or more would be shocked to learn that during all this time FDA has had jurisdiction to regulate cigarettes as drugs, and presumably to ban them.*

Id. at 40 (emphasis added).

As FDA and the Justice Department recognized, any change in such a longstanding interpretation would be contrary to clear congressional intent:

> Although it has amended the Act many times, Congress has never acted to disturb the agency's interpretation. In such circumstances, the Supreme Court has recognized Congressional acquiescence in the FDA's construction of the Act.

Id. at 27 n.23 (citation omitted).

These arguments prevailed. *See ASH*, 655 F.2d at 236. The court of appeals expressly endorsed the statutory interpretation that the pharmacological effects of nicotine do *not* provide a basis for FDA jurisdiction. *Id.* at 240.

In 1978, ASH again petitioned FDA, this time arguing that filtered cigarettes are intended to mitigate or prevent disease and thus were medical "devices" under the FDCA. *Citizen Petition*, Dkt. No. 78P-0338 (Oct. 2, 1978). However, FDA concluded that it is

> not reasonable to consider cigarettes as "devices" when there was no discussion in the legislative history of congressional intent to provide jurisdiction over cigarettes or to provide authority suitable to the regulation of cigarettes.

Novitch Letter, Jt. App. at 54. Thus, "[i]nsofar as rulemaking would relate to cigarettes . . . as customarily marketed, . . . *FDA has no jurisdiction* [and] *no rulemaking is permissible as a matter of law.*" *Id.* at 67 (emphasis added). FDA recognized that its lack of jurisdiction was inherent in the FDCA and not due to a lack of evidence or an exercise of administrative discretion.[16]

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[16] While the ASH petitions were before the Agency, five bills were introduced to grant FDA jurisdiction over cigarettes. H.R. 2419, 95th Cong. (1977); H.R. 3879, 95th Cong. (1977); H.R. 7168, 95th Cong. (1977); S. 3317, 95th Cong. (1978); H.R. 279, 96th Cong. (1979). None was enacted.

D. During the 1980s and 1990s, Congress Supplemented Its Regulatory Program for Tobacco Products in Ways Squarely Inconsistent with FDA Jurisdiction.

Congress has continued to refine its program for tobacco regulation through legislation *specifically* addressing aspects of a product that even FDA has recognized raises "unique" issues. 61 Fed. Reg. 44,396, 44,404 (1996).

In 1983, Congress required the Secretary of HHS to report to Congress every three years on the "addictive property of tobacco," and to include recommendations for action that the Secretary may deem appropriate. Alcohol and Drug Abuse Amendments of 1983, Pub. L. No. 98-24, §2(b)(7), 97 Stat. 175, 178 (1983), *codified at* 42 U.S.C. § 290aa *et seq.*

The next year, Congress again amended the FCLAA to modify the prescribed warning for cigarettes, reaffirming that the FTC—not FDA—would continue to administer this requirement. *See* Comprehensive Smoking Education Act of 1984, Pub. L. No. 98-474, 98 Stat. 2200 (1984), *amending* 15 U.S.C. § 1331 *et seq.* In the opening hearing, Chairman Waxman of the House Subcommittee on Health and the Environment, a proponent of increased tobacco regulation, remarked:

> The [FDA] is charged with assuring that the public is adequately warned about the health effects of drugs and that hazardous foods and drugs are removed from the market. *Yet, no Federal agency has jurisdiction over cigarettes. . . . The responsibility to regulate the cigarette industry falls to the Congress.*

Smoking Prevention Education Act: Hearings on H.R. 1824 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce, 98th Cong. 1 (1983) (emphasis added).

Assistant Secretary for Health Brandt, speaking on behalf of FDA, agreed: "[T]he issue of regulation of tobacco . . . is *something that Congress has reserved to itself*, and we do not . . . have the authority to regulate nor are we seeking such authority." *Id.* at 74 (emphasis added). Dr. Brandt repeated this understanding to the Senate: "Our view is that the Congress has assumed the responsibility of regulating . . . cigarettes." *Smoking Prevention Health and Education Act of 1983: Hearings on S. 772 Before the Comm. on Labor and Human Resources*, 98th Cong. 56 (1983).

The House committee with jurisdiction over FDA agreed: "Federal laws that protect the public from hazardous food, drugs and consumer products do not apply to cigarettes . . . ." H.R. Rep. No. 98-805, 12 (1984).

As part of these FCLAA amendments, Congress also required cigarette manufacturers to "annually provide the Secretary [of HHS] with a list of the ingredients added to tobacco in the manufacture of cigarettes . . . ." 15 U.S.C. § 1335a(a). This section—which authorizes the Secretary to report directly to Congress on the health effects of those ingredients—reflected Congress' concern that

> [a]t the present time, cigarette manufacturers are not statutorily required to disclose to any agency or department of the federal government any of the ingredients they place in cigarettes during the manufacturing process.

H.R. Rep. No. 98-805, 21 (1984). This statement shows that FDA lacks jurisdiction over tobacco products.

In 1986, Congress enlarged its national tobacco program when it passed the Comprehensive Smokeless Tobacco Health Education Act ("CSTHEA"), Pub. L. No. 99-252, 100 Stat. 30 (1986), *codified at* 15 U.S.C. § 4401 *et seq.*, relying in part on the fact that "FDA claims [that]

it does not have the authority to regulate the sale of smokeless tobacco." *Tobacco Issues: Hearings on H.R. 2835, H.R. 760, H.R. 2950, and H.R. 3078, Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 99th Cong. 106 (1985) (statement of Rep. Synar). The CSTHEA bans broadcast advertising of smokeless tobacco products, establishes a mandatory warning format, and authorizes the FTC—not FDA—to issue implementing regulations. 15 U.S.C. §§ 4401-08. The CSTHEA thus rests on the same fundamental policy embodied in the FCLAA—that informed adults should be permitted to decide whether or not to use tobacco products.[17]

In 1988, the Surgeon General declared that nicotine is "addictive". U.S. Dep't of Health and Human Services, Public Health Service, *The Health Consequences of Smoking: Nicotine Addiction, A Report of the Surgeon General* (1988); *see also* U.S. Dep't of Health and Human Services, Public Health Service, *Reducing the Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General*, 10 (1989) ("1989 Surgeon General Report").

Rep. Durbin brought the "addiction" issue to the attention of the House:

> Congress declares war on addictive drugs, yet we virtually ignore one of the greatest causes of addiction in America: Tobacco. We regulate food and drugs to protect the health of our citizens, but we *specifically exempt* the cause of 350,000 American deaths each year: Tobacco. . . . *The Congress should change the Food, Drug and Cosmetic Act to define nicotine as a drug.* That would make all

[17] In 1987, Congress failed to enact yet another bill that would have expanded FDA jurisdiction to cover tobacco products. *See* H.R. 3294, 100th Cong. (1987).

> tobacco products subject to regulation by the FDA, *allowing us to restrict sales to children . . . .*

134 Cong. Rec. 11,261 (1988) (emphasis added).[18]

The next year, two bills were introduced in both Houses to amend the FDCA to give FDA jurisdiction over tobacco products. *See* H.R. 1494, 101st Cong. (1989); S. 769, 101st Cong. (1989). Again, Congress did not enact either of them even though their proponents argued that the issues of youth smoking and "addiction"—the same issues that FDA itself now advances—called for expanded FDA jurisdiction:

> [E]very day, more than 3,000 American teenagers—or 60 percent of all new smokers—start smoking. Yet . . . tobacco products are largely exempted from the laws we have established to protect the public from unsafe consumer products. All of this despite that fact that we now know without question that cigarettes and other tobacco products containing nicotine are highly addictive.

135 Cong. Rec. 6,550 (1989) (statement of Rep. Durbin).

Even after the Surgeon General reported in 1988 that nicotine in tobacco products is addictive, FDA Commis-

[18] Respondents' history of Congress' consideration of tobacco product legislation between 1964 and 1988 is consistent with that of the Surgeon General:

> Following the 1964 Surgeon General's Report, Congress considered a number of bills to regulate tobacco [including] amending the FFDCA to place cigarettes under the authority of the FDA. Because there was no known safe level for tar, nicotine or other tobacco constituents, regulation would have likely resulted in prohibition. . . . Instead, following considerable debate [Congress enacted the FCLAA]

1989 Surgeon General Report at 605, 612-613 (noting further that, rather than "allowing regulation by Federal agencies, Congress in most cases reserved to itself jurisdiction over tobacco products. . . .").

sioner Young testified that "it doesn't look like it is possible to regulate [tobacco] under the [FDCA] even though smoking, I think, has been widely recognized as being harmful to human health." *Rural Development, Agriculture, and Related Agencies Appropriations for 1989: Hearings Before a Subcomm. of the House Comm. on Appropriations,* 100th Cong. 409 (1989). Rep. Durbin agreed: "I think the legal interpretation is fairly clear that tobacco is not included in your legislative mandate." *Id.*

Commissioner Young's reaffirmation of FDA's long-held view that it does not have jurisdiction over cigarettes prompted some Members of Congress to call for new statutory restrictions on cigarette advertising. In 1990, for example, Rep. Waxman sponsored a bill that would have made it a federal offense to distribute free tobacco-product samples, sponsor sporting events using cigarette brand names, or advertise in anything other than a black-and-white format. *See* H.R. 5041, 101st Cong. (1990). The House Commerce Committee did not report the proposed legislation, yet these same unenacted restrictions are now found in FDA's current regulations. *See* 21 C.F.R. §§ 897.16(d), 897.34(c), 897.32.[19]

In response to such concerns about youth and tobacco, Congress expanded its tobacco program in 1992 by enacting the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act of 1992 ("ADAMHA Amendments"). Pub. L. No. 102-321, Title II, § 202, 106 Stat. 394, *codified at* 42 U.S.C. § 300x-26. Through these Amendments, Congress determined that the States—not the federal government—should remain responsible for re-

[19] These restrictions were rejected by the same Congress that enacted the Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511-30 (1990), which FDA claims supports its authority to impose some of the same restrictions in the guise of regulating tobacco products as "devices."

stricting underage access to tobacco products: The federal government creates incentives for the States to pursue their traditional role of regulating the retail sale of tobacco products by withholding funds from States that fail to enact or adequately enforce their own laws prohibiting tobacco product sales to minors.[20]

In the ADAMHA Amendments, Congress sought to preserve State flexibility and declined to "force a particular standard upon all states," 58 Fed. Reg. 45,156, 45,161 (1993) (proposed implementing regulations).

> [E]ach State should have the flexibility to enforce its laws in a manner that can reasonably be expected to reduce availability of tobacco products to minors in light of that State's own unique circumstances.

61 Fed. Reg. 1492, 1495. (1996). Yet, soon after the ADAMHA regulations were finalized, FDA seized jurisdiction and announced its own uniform national tobacco-access requirements, thereby supplanting Congress' program.

E. Following the 1994 Elections, FDA Abruptly Decided to Regulate Tobacco Products Without Congressional Authorization.

In 1994, FDA announced that it would "work with Congress" to consider whether the Agency could assert jurisdiction over cigarettes as "drugs." FDA expressly recognized that it was "vital" that "Congress provide clear direction to the agency" because "the regulation of cigarettes raises societal issues of great complexity and mag-

[20] In 1992, legislation was also introduced—H.R. 4350 and S. 2298, 102d Cong. (1992)—to expand FDA jurisdiction by creating a new regulatory category for tobacco products. Rep. Synar observed that FDA "is powerless to do anything" about tobacco products. 138 Cong. Rec. 4028-29 (1992). Again, in 1993, two more bills were introduced that would have expanded FDA jurisdiction to include tobacco products. H.R. 2147 and S. 672, 103d Cong. (1993). None of these bills passed.

nitude." Letter from FDA Comm'r Kessler to Ballin (Feb. 25, 1994), in *Regulation of Tobacco Products (Part I), Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 103rd Cong. 3, 25 (1994) ("*1994 Hearings*"). *See also 1994 Hearings* at 73 (statement of Comm'r Kessler seeking "guidance from the Congress").

FDA quickly lost interest in working with Congress following the November 1994 election that resulted in a change in the political control of Congress. One day after that election, the Agency announced that "FDA will make" the decision on its jurisdiction over tobacco products. Letter from FDA Assoc. Comm'r Thompson to Rep. Lancaster 2 (Nov. 10, 1994).[21] Thereafter, without any direction—much less authorization—from Congress, FDA asserted jurisdiction over tobacco products.[22] FDA Deputy Commissioner Shultz candidly described this decision as "historic" precisely "because it provided an opportunity for taking decisive action on tobacco without requiring action by Congress." Schultz, *The FDA's Decision to Regulate Tobacco Products*, 18 Pace L. Rev. 27, 29 (1997).

FDA's excuse for its abrupt about face is its contention that it has unearthed "new facts" showing that nicotine is an addictive drug.[23] Even if those "new facts" had legal

21 While FDA reconsidered asserting jurisdiction over tobacco products, Congress excluded them from the definition of "dietary supplement," which otherwise included any "botanical product," in the Dietary Supplement Health and Education Act ("DSHEA"), Pub. L. No. 103-417 § 3, 108 Stat. 4325, 4327 (1994). The exclusion was unnecessary, but it precluded FDA from using the DSHEA to reach tobacco products as dietary supplements.

22 Two months before FDA proposed its tobacco rule, a bill was introduced to give FDA new authority to regulate tobacco products. H.R. 1853, 104th Cong. (1995). The bill was not enacted.

23 Under FDA's new interpretation of "drug", neither "addiction" nor any other particular pharmacological effect is necessary for FDA jurisdiction. Any kind of physical effect on the body would suffice, including the many kinds of adverse effects ascribed to tobacco products in the 1964 Surgeon General's Report.

relevance, which they do not, FDA's explanation does not withstand scrutiny. Pharmacological effects of nicotine have been well known for decades. Indeed, they were known in 1938 when Congress enacted the FDCA, were catalogued in the 1964 Surgeon General's Report, and were extensively discussed in the 1979 report by the National Institute of Drug Abuse which concluded that cigarettes are addictive. *See* notes 4 and 11, *supra*; National Institute on Drug Abuse, *The Behavioral Aspects of Smoking* (1979), *reprinted in* Dep't of Health, Education, and Welfare, Public Health Service, *Smoking and Health, A Report of the Surgeon General*, ch. 15 (1979). These facts are not new.[24] The only thing new is FDA's willingness to ignore statutory restraints.

F. Congress Continues to Address Smoking and Health Issues.

In the last Congress, legislation to grant FDA jurisdiction over tobacco products was considered on the

24 FDA acknowledged that the "long history of tobacco and nicotine use for pharmacological purposes" was "well known to the tobacco industry," an acknowledgement it based on a study *published* in 1965. 60 Fed. Reg. 41,314, 41,621 n.240 (1995). FDA also relied on many other *published studies* about the tobacco industry's knowledge of pharmacological effects of nicotine from the 1950s through the 1970s. *See* 61 Fed. Reg. 44,396, 44,895-912, 44,952-53 (1996). Given FDA's claim that foreseeability of pharmacological effects has always established the requisite intended use of a product to affect the structure or function of the body, Pet. Br. at 4, the basis for FDA's current theory of jurisdiction has existed for many decades.

The Government asserts that "basic drug-like qualities [of tobacco products] are so well documented, widely known and thoroughly embedded in the behavior of consumers and manufacturers," that express claims to that effect would be "superfluous." Pet. Br. at 25. Apparently, FDA's argument is that until 1995 everyone was aware of these facts except FDA.

arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: *Provided*, That to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: *Provided*, That the method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States, and not to those of the United States Pharmacopoeia.

(h) If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form

and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i)(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

EXEMPTIONS IN CASE OF DRUGS AND DEVICES

SEC. 503. (a) The Secretary is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

(b) A drug dispensed on a written prescription signed by a physician, dentist, or veterinarian (except a drug dispensed in the course of the conduct of a business of dispensing drug pursuant to diagnosis by mail), shall if—

(1) such physician, dentist, or veterinarian is licensed by law to administer such drug, and

(2) such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian,

be exempt from the requirements of section 502 (b) and (e), and (in case such prescription is marked by the writer thereof as not refillable or its refilling is prohibited by law) of section 502 (d).

CERTIFICATION OF COAL-TAR COLORS FOR DRUGS

SEC. 504. The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in drugs for purposes of coloring only and for the certification of batches of such colors, with or without harmless diluents.

NEW DRUGS

SEC. 505. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for,

the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

(c) An application provided for in subsection (b) shall become effective on the sixtieth day after the filing thereof unless prior to such day the Secretary by notice to the applicant in writing postpones the effective date of the application to such time (not more than one hundred and eighty days after the filing thereof) as the Secretary deems necessary to enable him to study and investigate the application.

(d) If the Secretary finds, after due notice to the applicant and giving him an opportunity for a hearing, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(e) The effectiveness of an application with respect to any drug shall, after due notice and opportunity for hearing to the applicant, by order of the Secretary be suspended if the Secretary finds (1) that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug is unsafe for use under the conditions of use upon the basis of which the application became effective, or (2) that the application contains any untrue statement of a material fact. The order shall state the findings upon which it is based.

(f) An order refusing to permit an application with respect to any drug to become effective shall be revoked whenever the Secretary finds that the facts so require.

(g) Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary or (2) by mailing the order by registered mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) An appeal may be taken by the applicant from an order of the Secretary refusing to permit the application to become effective, or suspending the effectiveness of the application. Such appeal shall be taken by filing in the district court of the United States within any district wherein such applicant resides or has his principal place of business, or in the District Court of the United States for the District of Columbia, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the record upon which the order complained

of was entered. Upon the filing of such transcript such court shall have exclusive jurisdiction to affirm or set aside such order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment and decree of the court affirming or setting aside any such order of the Secretary shall be final, subject to review as provided in sections 128, 239, and 240 of the Judicial Code, as amended (U. S. C., 1934 ed., title 28, secs. 225, 346, and 347), and in section 7, as amended, of the Act entitled "An Act to establish a Court of Appeals for the District of Columbia", approved February 9, 1893 (D. C. Code, title 18, sec. 26). The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i) The Secretary shall promulgate regulations for exempting from the operation of this section drugs intended

solely for investigational use by experts qualified by scientific training and experience to investigate the safety of drugs.

CHAPTER VI—COSMETICS

ADULTERATED COSMETICS

SEC. 601. A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: *Provided*, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 604.

MISBRANDED COSMETICS

SEC. 602. A cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

REGULATIONS MAKING EXEMPTIONS

SEC. 603. The Secretary shall promulgate regulations exempting from any labeling requirement of this Act cosmetics which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial

quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

CERTIFICATION OF COAL-TAR COLORS FOR COSMETICS

SEC. 604. The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in cosmetics and for the certification of batches of such colors, with or without harmless diluents.

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

SEC. 701. (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

(b) The Secretary of the Treasury and the Secretary of Agriculture shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Agriculture shall determine.

(c) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(d) The definitions and standards of identity promulgated in accordance with the provisions of this Act shall

be effective for the purposes of the enforcement of this Act, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e) The Secretary, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of this Act: 401, 403 (j), 404 (a), 406 (a) and (b), 501 (b), 502 (d), 502 (h), 504, and 604. The Secretary shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less than thirty days after the date of the notice, except that the public hearing on regulations under section 404 (a) may be held within a reasonable time, to be fixed by the Secretary, after notice thereof. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Secretary shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take such action. The Secretary shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. No such order shall take effect prior to the ninetieth day after it is issued, except that if the Secretary finds that emergency conditions exist necessitating an earlier effective date, then the Secretary shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Secretary shall specify therein to meet the emergency.

(f)(1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. The summons and petition may be served at any place in the United States. The Secretary, promptly upon service of the summons and petition, shall certify and file in the court the transcript of the proceedings and the record on which the Secretary based his order.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) The court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such

regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this Act, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

EXAMINATIONS AND INVESTIGATIONS

SEC. 702. (a) The Secretary is authorized to conduct examinations and investigations for the purposes of this Act through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department. In the case of food packed in a Territory the

Secretary shall attempt to make inspection of such food at the first point of entry within the United States when, in his opinion and with due regard to the enforcement of all the provisions of this Act, the facilities at his disposal will permit of such inspection. For the purposes of this subsection the term "United States" means the States and the District of Columbia.

(b) Where a sample of a food, drug, or cosmetic is collected for analysis under this Act the Secretary shall, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this Act.

(c) For purposes of enforcement of this Act, records of any department or independent establishment in the executive branch of the Government shall be open to inspection by any official of the Department of Agriculture duly authorized by the Secretary to make such inspection.

RECORDS OF INTERSTATE SHIPMENT

SEC. 703. For the purpose of enforcing the provisions of this Act, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity,

shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates: *Provided*, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained: *Provided further*, That carriers shall not be subject to the other provisions of this Act by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers.

FACTORY INSPECTION

SEC. 704. For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, after first making request and obtaining permission of the owner, operator, or custodian thereof, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or are held after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

PUBLICITY

SEC. 705. (a) The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof.

(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. Nothing in this secton shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

COST OF CERTIFICATION OF COAL-TAR COLORS

SEC. 706. The admitting to listing and certification of coal-tar colors, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

CHAPTER VIII—IMPORTS AND EXPORTS

SEC. 801. (a) The Secretary of the Treasury shall deliver to the Secretary of Agriculture, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Agriculture and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505, then such article shall be refused admission. This paragraph shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under section 2 of the Act of May 26, 1922, as amended (U.S.C., 1934 edition, title 21, sec. 173).

(b) The Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any such article refused admission, unless such article is exported by the consignee within three months from the date of notice of such refusal, under such regulations as the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee any such article pending examination and decision in the matter on execution of a bond as liquidated damages for the amount of the full invoice value thereof together with the duty thereon and on refusing for any cause to return such article or any part thereof to the custody of the Secretary of the Treasury when demanded for the purpose of excluding it from the country or for any other purpose, such consignee shall forfeit the full amount of the bond as liquidated damages.

(c) All charges for storage, cartage, and labor on any article which is refused admission or delivery shall be paid by the owner or consignee and in default of such payment shall constitute a lien against any future importations made by such owner or consignee.

(d) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it (1) accords to the specifications of the foreign purchaser, (2) is not in conflict with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the shipping package to show that it is intended for export. But if such article is sold or offered for sale in domestic commerce, this subsection shall not exempt it from any of the provisions of this Act.

CHAPTER IX—MISCELLANEOUS

SEPARABILITY CLAUSE

SEC. 901. If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

EFFECTIVE DATE AND REPEALS

SEC. 902. (a) This Act shall take effect twelve months after the date of its enactment. The Federal Food and Drugs Act of June 30, 1906, as amended (U. S. C., 1934 ed., title 21, secs. 1-15), shall remain in force until such effective date, and, except as otherwise provided in this subsection, is hereby repealed effective upon such date: *Provided*. That the provisions of section 701 shall become effective on the enactment of this Act, and thereafter the Secretary is authorized hereby to (1) conduct hearings and to promulgate regulations which shall become effective on or after the effective date of this Act as the Secretary shall direct, and (2) designate prior to the effective date of this Act food having common or usual names and exempt such food from the requirements of clause (2) of section 403 (i) for a reasonable time to permit the formulation, promulgation, and effective application of definitions and standards of identity therefor as provided by section 401: *Provided further,* That sections 502 (j), 505, and 601 (a), and all other provisions of this Act to the extent that they may relate to the enforcement of such sections, shall take effect on the date of the enactment of this Act, except that in the case of a cosmetic to which the proviso of section 601 (a) relates, such cosmetic shall not, prior to the ninetieth day after such date

of enactment, be deemed adulterated by reason of the failure of its label to bear the legend prescribed in such proviso: *Provided further*, That the Act of March 4, 1923 (U. S. C., 1934 ed., title 21, sec. 6; 42 Stat. 1500, ch. 268), defining butter and providing a standard therefor; the Act of July 24, 1919 (U. S. C., 1934 ed., title 21, sec. 10; 41 Stat. 271, ch. 26), defining wrapped meats as in package form; and the amendment to the Food and Drugs Act, section 10A, approved August 27, 1935 (U. S. C., 1934 ed., Sup. III, title 21, sec. 14a), shall remain in force and effect and be applicable to the provisions of this Act.

(b) Meats and meat food products shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended (U. S. C., 1934 ed., title 21, secs. 71-91; 34 Stat. 1260 et seq.).

(c) Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the virus, serum, and toxin Act of July 1, 1902 (U. S. C., 1934 ed., title 42, chap. 4); the Filled Cheese Act of June 6, 1896 (U. S. C., 1934 ed., title 26, ch. 10), the Filled Milk Act of March 4, 1923 (U. S. C., 1934 ed., title 21, ch. 3, secs. 61-63); or the Import Milk Act of February 15, 1927 (U. S. C., 1934 ed., title 21, ch. 4, secs. 141-149).

(d) In order to carry out the provisions of this Act which take effect prior to the repeal of the Food and Drugs Act of June 30, 1906, as amended, appropriations available for the enforcement of such Act of June 30, 1906, are also authorized to be made available to carry out such provisions.

Approved, June 25, 1938.

21 U.S.C. § 321(p)(1) provides as follows:

§ 321. Definitions; generally

* * * *

(p) The term "new drug" means—

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use . . . .

21 U.S.C. §§ 351(b) and (c) provides as follows:

§ 351. Adulterated drugs and devices

A drug or device shall be deemed adulterated—

* * * *

(b) Strength, quality, or purity differing from official compendium

If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary, shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay have not been prescribed in such comtary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United

States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(c) Misrepresentation of strength, etc., where drug is unrecognized in compendium

If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

21 U.S.C. § 352(e)(1) provides as follows:

§ 352. Misbranded drugs and devices

A drug or device shall be deemed to be misbranded—

* * * *

(e) Designation of drugs or devices by established names

(1)(A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—

(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name,

(ii) the established name and quantity, or if determined to be appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if determined by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein, except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subclause, shall not apply to nonprescription drugs not intended for human use; and

(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if determined to be appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, ex-

cept that nothing in this subclause shall be deemed to require that any trade secret be divulged, and except that the requirements of this subclause with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics and that this subclause shall not apply to nonprescription drugs not intended for human use.

(B) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient, except that to the extent that compliance with the requirements of subclause (ii) or (iii) of clause (A) or this clause is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

21 U.S.C. § 353(b)(1) provides as follows:

§ 353. Exemptions and consideration for certain drugs, devices, and biological products

* * * *

(b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

(1) A drug intended for use by man which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug;

shall be dispensed only (i) upon written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such pracitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

21 U.S.C. § 360c(a)(1)-(2) provides as follows:

§ 360c. Classification of devices intended for human use

(a) Classes of devices

(1) There are established the following classes of devices intended for human use:

(A) CLASS I, GENERAL CONTROLS.—

(i) A device for which the controls authorized by or under section 351, 352, 360, 360f, 360h, 360i, or 360j of this title or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it—

(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and

(II) does not present a potential unreasonable risk of illness or injury.

is to be regulated by the controls referred to in clause (i).

(B) CLASS II, SPECIAL CONTROLS.— A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide

such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 360(k) of this title), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C) CLASS III, PREMARKET APPROVAL.— A device which because—

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient informaton exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

(ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

(2) For purposes of this section and sections 360d and 360e of this title, the safety and effectiveness of a device are to be determined—

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.